



**IN THE UNITED STATES PATENT  
AND TRADEMARK OFFICE**

Appln. No. : 10/606,632

Applicant(s) : Masaya TAKAOKA et al.

Filed : June 26, 2003

For : MEDICINAL COMPOSITIONS  
CONTAINING DIURETIC AND  
INSULIN RESISTANCE-  
IMPROVING AGENT

Art Unit : 1614

Examiner :

Docket No. : 03260CIP/HG

Confirm. No. : 4979

Customer No. : 01933

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Date of Deposit: April 29, 2004

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*Lorraine Dobies*  
Lorraine Dobies

In the event that this Paper is late filed, and the necessary petition for extension of time is not filed concurrently herewith, please consider this as a Petition for the requisite extension of time, and to the extent not tendered by check attached hereto, authorization to charge the extension fee, or any other fee required in connection with this Paper to Account No. 06-1378.

**INFORMATION DISCLOSURE STATEMENT**

COMMISSIONER FOR PATENTS  
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S I R :

Submitted herewith are the following:

- (1) Copy of Search Report/Official Action issued in the European application corresponding to the present application;
- (2) Copies of the cited publications; and
- (3) Forms PTO/SB/08A and PTO/SB/08B. It is requested that an initialed copy of the forms PTO/SB/08A and PTO/SB/08B be returned to indicate that the publications listed therein have been considered and made of record.

All of the references are in English.

Each of the documents is considered relevant because of its citation in the enclosed Search Report and for the reasons stated therein.

No Patent Office late fee is required because a first Office Action on the merits has not yet issued. If it is determined that a fee is required, please charge our Account No. 06-1378.

It is respectfully requested that the attached publications be considered and made "of record".

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Respectfully submitted,

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Reg. No. 26,853

Encs.: Form PTO/SB/08A and PTO/SB/08B and publications listed thereon  
European Search Report

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PTO/SB/08A (08-00)

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

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|---|------------------------|----------------------|----------------|
| Substitute for Form 1449A/PTO<br><br>INFORMATION DISCLOSURE<br>STATEMENT BY APPLICANT<br><br><i>O P E S</i><br><i>APR 29 2004</i> |                        | Application Number   | 10/606,632     |
|   |                        | Filing Date          | June 26, 2003  |
|   |                        | First Named Inventor | Masaya TAKAOKA |
|   |                        | Group Art Unit       | 1614           |
|   |                        | Examiner Name        |                |
| Sheet <i>1</i> of <i>2</i>  | Attorney Docket Number | 03260CIP/HG          |                |

### U.S. PATENT DOCUMENTS

| Exam.<br>Inits* | Cite<br>No <sup>1</sup> | Document Number | Kind<br>Code <sup>2</sup> | Name of Patentee or<br>Applicant | Publication<br>Date MM-DD-YYYY | Relevant<br>Portion |
|-----------------|-------------------------|-----------------|---------------------------|----------------------------------|--------------------------------|---------------------|
|                 |                         | 5,457,109       | A                         | Antonucci et al.                 | 10-10-1995                     |                     |

### FOREIGN PATENT DOCUMENTS

| Exam.<br>Inits* | Cite<br>No <sup>1</sup> | Offc <sup>3</sup> | Document Number <sup>4</sup> | Kind<br>Code <sup>5</sup> | Name of Patentee or<br>Applicant | Publication<br>Date MM-DD-YYYY | Relevant<br>Portion | T <sup>6</sup> |
|-----------------|-------------------------|-------------------|------------------------------|---------------------------|----------------------------------|--------------------------------|---------------------|----------------|
|                 |                         | PCT               | WO 01/47509                  | A2                        | SmithKline Beecham               | 07-05-2001                     |                     |                |

Examiner  
Signature

Date  
Considered

\* EXAMINER: Initial if document considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Unique citation designation number. <sup>2</sup> See kinds of U.S. Patent Documents. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Place a check here if English translation is attached.

DATE MAILED: April 29, 2004

|  |   |                        |                |
|--|---|------------------------|----------------|
| <b>INFORMATION DISCLOSURE<br/>STATEMENT BY APPLICANT</b> |   | Application Number     | 10/606,632     |
|  |   | Filing Date            | June 26, 2003  |
|  |   | First Named Inventor   | Masaya TAKAOKA |
|  |   | Group Art Unit         | 1614           |
|  |   | Examiner Name          |                |
| Sheet  | 2 | of                     | 2              |
|  |   | Attorney Docket Number | 03260CIP/HG    |

**OTHER DOCUMENTS - NON-PATENT LITERATURE DOCUMENTS**

| Examiner Initials <sup>1</sup> | Cite No. <sup>1</sup> | Include name of author (in CAPITAL LETTERS), title of article, title of item, date, page(s), volume-issue number(s), publisher, city and/or country where published  | T <sup>2</sup> |
|--------------------------------|-----------------------|--|----------------|
|                                |                       | <p>HOSOKAWA, et al., "Troglitazone Inhibits Bicarbonate Secretion in Rat and Human Duodenum", <u>Journal of Pharmacology and Experimental Therapeutics</u>, <u>The American Society for Pharmacology and Experimental Therapeutics</u>, September 1999, pp. 1080-1084, XP008002057, ISSN: 0022-3565, vol. 3, No. 290, USA</p> <p>DAGOGO-JACK, et al., "Pathophysiology of Type 2 Diabetes and Modes of Action of Therapeutic Interventions", <u>Archives of Internal Medicine</u>, <u>American Medical Association</u>, September 8, 1997, pp. 1802-1817, XP000872498, ISSN: 0003-9926 vol. 157, No. 16, Chicago, IL</p> <p>GILBERT et al., "Drug Administration in Patients with Diabetes Mellitus-Safety Considerations", <u>Drug Safety</u>, (1998), pp. 441-455, vol. 18, No. 6, XP001041098, ISSN: 0114-5916, Adis Press, Auckland NZ</p> |                |
| Examiner Signature             |                       | Date Considered  |                |

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